UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,879	06/21/2001	Avi J. Ashkenazi	P1110P1C1	9003

9157 7590 12/19/2007

GENENTECH, INC.
1 DNA WAY
SOUTH SAN FRANCISCO, CA 94080

EXAMINER	
KAUFMAN, CLAIRE M	

ART UNIT	PAPER NUMBER
1646	

MAIL DATE	DELIVERY MODE
12/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/887,879	ASHKENAZI ET AL.	
	Examiner	Art Unit	
	Claire Kaufman	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-34, 55-68* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *29-34 and 61-68* is/are allowed.

6)☒ Claim(s) *55-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/19/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Prosecution is continued in this application after granting the petition filed 10/17/06 to revive this application after abandonment. As a result, claims filed 10/3/07 are pending and Applicants' argument submitted 8/23/07 are under consideration.

Response to Arguments

The rejection of claims under provisional double patenting over claims in application 10/242,383 is moot because, as pointed out by Applicants, application 10/242,383 is no longer pending.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 55-60 remain rejected under 35 U.S.C. 102(e) as being anticipated by Patent 6,261,801 (Wei et al.) for the reasons set forth in the previous Office action mailed 12/23/05.

Upon further reconsideration by the examiner, claims 61-62 and 67-68 are no longer rejected as anticipated by US 6,261,801, because while the priority applications for the patent disclose aTNFR-5 antagonist and an antagonistic function of reducing selective killing of CD4 T-lymphocytes in HIV+ individuals, there is no means of determining the presence of a blocking antibody to the receptor itself. That is, the binding of an antibody that blocks the binding of a ligand to TNFR-5 requires either the presence of an detectable ligand or the ability to inhibit the activity of the receptor to which it binds. US 60/035,496 of the patent does not specifically disclose the ligand to which the receptor binds nor an activity of the activated receptor that could

be blocked and, therefore, used to identify a blocking antibody.

Applicants argue that the 6,261,801 ('801) discloses only certain sequences for TNFR-5 and speculative and prophetic uses for TNFR-5, but does not have an enabling disclosure for TNFR-5 or characterization of the TNFR-5 molecule. Applicants support this by pointing to the list of diverse diseases for which TNFR-5 is purported to be useful in treating. Additionally, '801 admits that the effects of TNF family of ligands and receptors are varied and numerous, which makes imputing a function or activity to TNFR-5 uncertain. The argument has been fully considered, but is not persuasive. While there are no actual examples of modulating apoptosis in mammalian cells using the TNFR-5 polypeptide nor is the mechanism by which TNFR-5 can induce apoptosis disclosed in '801, the antibody is taught. Further, the great majority of uses of TNFR-5 disclosed in the patent involve inhibition of apoptosis (inflammation, arthritis, septicemia, autoimmune disease, transplant rejection, graft *v.* host disease, infection, stroke, ischemia, acute respiratory disease syndrome, brain injury and AIDS (col. 2, lines 40-45)). An actual reduction to practice is not required for this to be an anticipatory reference. According to MPEP § 2122, utility need not be disclosed in a reference. "In order to constitute anticipatory prior art, a reference must identically disclose the claimed compound, but no utility need be disclosed by the reference. In re Schoenwald, 964 F.2d 1122, 22 USPQ2d 1671 (Fed. Cir. 1992)." Further, as stated in MEPE § 2121.01, the courts have found that:

> "In determining that quantum of prior art disclosure which is necessary to declare an applicant's invention not novel' or anticipated' within section 102, the stated test is whether a reference contains an enabling disclosure'... ." In re Hoeksema, 399 F.2d 269, 158 USPQ 596 (CCPA 1968). A reference contains an "enabling disclosure" if the public was in possession of the claimed invention before the date of invention. "Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his [or her] own knowledge to make the claimed invention." In re Donohue, 766 F.2d 531, 226 USPQ 619 (Fed. Cir. 1985)

In the instant case, '801 provides all that is necessary for the artisan of ordinary skill at the time the invention was made to practice the claimed invention.

It is argued that in provisional application 60/035,496, the utility of selective reduction of killing of CD4 T-lymphocytes in HIV+ individuals by administration of an antagonist was

complexity and unpredictability of the HIV field. The argument have been fully considered, but remain not persuasive for the reasons of record. It is maintained that the patent's priority documents meet the written description and the enablement requirement because each teaches the protein (TNFR-5, a.k.a. Apo-2DcR), encoding nucleic acid, antibody to the protein and an antagonist which can be an antibody, as well as how to make and use the protein. Even though the provisional application's specification refers to the varied effects of the TNF family of ligands and receptors, and even though the antagonist effect on T-lymphocytes was not confirmed by experimentation, the specification's assertion was correct. A prophetic statement is sufficient if correct. It is noted that the structural limitations in the instant application's claims are an inherent property of the receptor polypeptide and antibody of the prior art.

Prior Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6,455,040 claims TNFR-5 antibodies and is by the same inventors as US 6,261,801 and is cumulative with that patent.

Interference

US Patent 6,455,040 has claims drawn to antagonist antibodies (*e.g.* claim 7). Applicants may wish to suggest an interference with this patent in view of the effective filing date of such claims.

Conclusion

Claims 29-34 and 61-68 are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (571) 272-0873. Dr. Kaufman can generally be reached Monday, Tuesday, Thursday and Friday from 9:30AM to 2:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached at (571) 272-0835.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Official papers filed by fax should be directed to (571) 273-8300. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Claire Kaufman, Ph.D.

Patent Examiner, Art Unit 1646

December 13, 2007

LORRAINE SPECTOR
PRIMARY EXAMINER